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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/617,489	07/10/2003	Thomas L. Cantor	532212000623	4476

25225 7590 10/23/2006

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EXAMINER	
CHEU, CHANGHWA J	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 10/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/617,489	CANTOR, THOMAS L.	
	Examiner	Art Unit	
	Jacob Cheu	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 September 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18,22-39 and 58-96* is/are pending in the application.

4a) Of the above claim(s) *1-9 and 60-80* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-18,22-39,58,59 and 81-96* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :9/8/2006; 6/14/2006; 5/5/2006; 4/19/2006; 1/13/2006.

DETAILED ACTION

Applicant's amendment filed on 9/8/2006 has been received and entered into record and considered.

The following information provided in the amendment affects the instant application:

1. Claims 19-21, 40-57 are cancelled.
2. Claims 91-96 are added.
3. Claims 1-9 and 60-80 are withdrawn from consideration.
4. Claims 10-18, 22-39, 58-59 and 81-96 are under examination.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 10-18, 22, 24-30, 58-59, 82-84, 85-87, 89-91 and 93-94, 96 are rejected under 35 U.S.C. 102(b) as being anticipated by Colford et al. (Endocrine Society 79th Meeting Abstract (1997) p3-194; applicant submitted IDS information filed 1/13/2006 #57).

Colford teaches polyclonal antibody directed to N-terminal PTH $_{1-7}$. Colford's PTH_{1-7} antibody binds to the N-terminal amino acids 1-7 of PTH. Colford teaches that the PTH_{1-7} is used in an assay for measuring the whole PTH in a sample. Colford compares well-known commercial assay kits and determined the presence of one or two immunoreactive PTH species (fragments) in addition to intact PTH, and PTH_{1-7} antibody binds only the intact PTH (showed only one peak). Thus, the assay used Colford PTH_{1-7} antibody does not bind to the non-whole PTH fragment in the sample (See Abstract; page IMU 3288, 3289 and 3297).

With respect to the feature of "detecting said whole PTH at a physiological level in said mammalian sample", PRODUCT, MPEP §2112 states "[Where] the claimed and prior art products are identical or substantially identical in *structure or composition*, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established." In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977)(emphasis added). Since the antibody disclosed by Colford et al. can detect whole PTH in hyperparathyroidism patient's serum as recited in the instant claims, it is inherent that antibodies from Colford et al. can also measure PTH at physiological levels.

With respect to claims 11-12, 14-15, 88, 93-94, Colford et al. teach detecting PTH levels from human PTH dysfunction patients. Supra.

With respect to claims 17-18, 85, 87, 89 and 96, the instant claims recite the antibody recognizing either human PTH $_{1\text{-}5}$, human PTH $_{1\text{-}6}$ or human PTH $_{1\text{-}8}$. Such features are within the scope of the Colford et al.'s teachings. Colford teaches polyclonal antibody directed to N-terminal PTH $_{1\text{-}7}$. Since epitopes are around 4-7 amino acids residues, therefore human PTH $_{1\text{-}5}$, $_{1\text{-}6}$ or $_{1\text{-}8}$ are within the scope of Colford's teachings.

With respect to claims 22, Colford et al. teach the non-whole PTH is a fragment of $PTH_{34\text{-}84}$. surpa.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claims 23 and 88 are rejected under 35 U.S.C. 103(a) as being unpatentable over Colford et al. in view of Lepage et al. (Clinical Chemistry 1998 Vol. 44, page 805).

Colford et al. reference has been discussed and a non-whole PTH_{34-84} has been used to detect the non-whole PTH. However Colford et al. do not explicitly teach using a PTH fragment 7-84 to detect the non-whole PTH level.

Lepage et al. teach a non-whole PTH_{7-84} circulating in the blood interfering with the measuring of the whole PTH level (See Abstract).

Therefore, it would have been obvious to one ordinary skill in the art at the time the invention was made to have provide Colford et al. with the non-whole PTH_{7-84} as taught by Lepage et al. in order to measure the true whole PTH levels not interfering with the non-whole PTH.

10. Claims 31-39, 81 and 84 are rejected under 35 U.S.C. 103(a) as being unpatentable over Colford et al..

Colford et al. reference has been discussed but does not explicitly teach measuring the physiological levels of PTH less than 4 pmole/L or from 7 picogram/ml to 39 picogram/ml.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to optimize the effectiveness from the selection of antibody clones, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

With respect to claims 33, 35, 38, Colford et al. teach measuring the ratios of whole PTH versus total (intact) PTH levels. Surpa.

11. Claims 92 and 95 are rejected under 35 U.S.C. 103(a) as being unpatentable over Colford et al. in view of Rucinski et al. (Calcified Tissue International 1995 Vol. 56, page 83).

Colford et al. teach detecting PTH levels in human serum samples. Colford et al. do not explicitly teach detecting rat or goat samples (See Abstract).

Rucinski et al. teach measuring rat and goat PTH levels by immunoassay methodology.

Therefore, it would have been obvious to one ordinary skill in the art at the time the invention was made to have provided Colford et al. with the alternative mammals, such as rat or goat as taught by Rucinski et al. since using alternative non-human mammals, such as rat or goat model is widely accepted and practiced in the field for better assessment of subsequent clinical significance on human.

Response to Applicant's Arguments

12. Applicant's arguments with respect to claims 10-18, 22-39, 58-59 and 81-96 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

13. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacob Cheu whose telephone number is 571-272-0814. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jacob Cheu
Examiner
Art Unit 1641

September 26, 2006

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